UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,216	06/13/2001	Robert E. Richard	12013/59001	4088

23838 7590 10/19/2004

KENYON & KENYON
1500 K STREET, N.W., SUITE 700
WASHINGTON, DC 20005

EXAMINER	
TSOY, ELENA	
ART UNIT	**PAPER NUMBER**
1762	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,216	RICHARD, ROBERT E.	
	Examiner	Art Unit	
	Elena Tsoy	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 21-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12-15* is/are allowed.

6)☒ Claim(s) *1-11 and 21-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. Amendment filed on August 31, 2004 has been entered. Claims 16-20 have been cancelled. New claims 23-32 have been added. Claims 1-15, 21-32 are pending in the application.

Claim Objections

2. Claim 24 is objected to because of the following informalities: "The method device of claim 1" should be changed to -- The method of claim 1 --.

Election/Restrictions

3. The Examiner agrees with Applicants that claims 12-15 were wrongly withdrawn from examination. Claims 12-15 are joined for examination.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-5, 7, 9, 11, 21, 22, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner (EP 405 284 A2) in view of Allen et al (US 6,495,204) and Smith (US 4,734,451).

Greiner teaches a method of coating a catheter medical device comprising mounting the catheter of e.g. polyurethane, in a reactor, adding therapeutic to the reactor, followed by adding carbon dioxide at a supercritical condition (i.e. interfacing therapeutic with supercritical fluid), cooling and depressurizing the reactor thereby transferring the therapeutic from supercritical fluid

(SCF) to the medical device (See examples 1, 4-7). In other words, Greiner's method is a batch soaking in an enclosed chamber.

Greiner fails to teach that: (i) the medical device can be coated by spray-on deposition (Claim 3) using nozzle (Claim 28) by combining therapeutic with SCF upstream of control valve and transporting the interfaced therapeutic within a conduit toward the medical device (Claim 1); vacuum force is applied to the reactor having the coated catheter (Claims 7, 21, 31); (ii) collecting residual SCF and therapeutic (Claims 9, 22).

As to (i), Allen et al teach that typically coating with the use of SCFs involves the application of one or more modifying agent by batch soaking in an enclosed chamber or includes processes based upon spraying from a pressurized chamber through a narrow nozzle (See column 1, lines 65-67). Upon spraying of the fluid onto the substrate, the supercritical fluid carrying the coating material leaves the high pressure environment and is exposed to a normal atmospheric environment. Examples of typical spray depositions of the prior art include US 4,734,451 to Smith See column 2, lines 1-25. The typical spray deposition, as shown at Fig. 4a of Smith, comprises combining coating material with SCF upstream of control valve (See column 14, lines 20-23), transporting the interfaced coating material within a conduit toward the medical device, spraying the interfaced coating material through nozzle 226 (See column 14, lines 9-10), and removing gas phase solvent by vacuum force (See column 13, lines 60+).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used spray-on deposition of Smith in Greiner instead of a batch soaking in an enclosed chamber since Allen et al teach that coating with the use of SCFs can be typically done either by a batch soaking in an enclosed chamber or by spray-on deposition such as of that of Smith.

As to (ii), Allen et al further teach that SCF and a coating material can be removed and recycled for further use (See column 6, lines 60-62).

As to claims 29-31, it is the Examiner's position that limitations of claims 29-31 would be within the level of ordinary engineering skill to achieve uniform covering of all areas of the device to be coated.

6. Claims 2, 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner (EP 405 284 A2) in view of Allen et al (US 6,495,204) and Smith (US 4,734,451), further in view of Scott et al (US 5,383,928), and further in view of Lambert (US 5,900,246) and Davidson (US 5,954,724).

Greiner in view of Allen et al and Smith, as applied above, fails to teach that: the method comprises applying a carrier coating to the medical device (Claims 2, 23); the method can be used for coating metallic medical device (Claim 24), stent (Claim 25), vena-cava filter (Claim 26), or aneurysm coil (Claim 27).

Scott et al teach that it is known in the art that the local delivery of drug(s) using stents can be done by directly coating the stent with a drug-polymer combination, or incorporating a drug directly into a stent of a biodegradable polymer, or coating first a metal stent with a polymer, then applying an anticoagulant compound to the coated stent (See column 3, lines 49-69). In other words, a secondary reference of Scott et al is relied upon to show that all three methods: coating a medical device with drug-polymer combination, incorporating a drug directly into a polymeric medical device, and coating a metal medical device first with a polymer, then applying drug to the medical device are functionally equivalent for the local delivery of drugs.

Davidson teaches that the same metal material can be used for making various medical devices including metalliic flexible catheters (See column 11, line 49), stents, vena cava filters,

aneurysm coils, needles (See column 11, lines 33-38), and can be coated with antibiotics, pro- or anti-thrombogenic agents, anti-inflammatory agents, morphogenic proteins, morphogenic peptides, growth factors, or stem cells to improve biocompatibility of the medical device (See column 11, lines 50-57). Lambert teaches that various medical devices including metallic stents or catheters (See column 3, lines 50-53) can be first coated with polyurethane and then contacting the coated device to with an expansion solution of a biologically active compound to swell the polyurethane polymer and incorporate the compound (See column 5, lines6-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used polyurethane coated metallic flexible catheter of Davidson and Lambert instead of polyurethane catheter of Greiner in a method of Greiner in view of Allen et al and Smith with the expectation of providing the desired local delivery of drug(s), since Scott et al teach that all three methods: coating a medical device with drug-polymer combination, incorporating a drug directly into a polymeric medical device, and coating a metal medical device first with a polymer, then applying drug to the medical device are functionally equivalent for the local delivery of drugs.

One of ordinary skill in the art at would have reasonable expectation of success in using a method of Greiner in view of Allen et al and Smith for coating any other metallic medical device including such as vena cava filters, aneurysm coils with the expectation of providing the desired local delivery of drugs since vena cava filters, aneurysm coils are of the same metal, as shown by Davidson and can be coated with a drug for the local delivery.

7. Claims 6, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner (EP 405 284 A2) in view of Allen et al (US 6,495,204) and Smith (US 4,734,451), further in view of Mehta et al (US 6,627,246).

The Examiner's Note: in contrast to Applicants Affidavit, Mehta et al has filing date of provisional application of **5/16/2000**, not of 4/17/2001. See MPEP 2136.03, III (page 2100-95).

Greiner in view of Allen et al and Smith, as applied above, fails to teach that: the therapeutic is colloidally suspended in SCF (Claim 6); the therapeutic is paclitaxel (Claim 10).

Smith further teaches that solubility of coating material is important for providing finer powders for forming very thin films (See column 9, lines 16-61). In other words, if there is no need for providing finer powders, coating materials, which do not form true solutions, any mixtures of therapeutic with SCF, e.g., colloidal solutions can be used.

Mehta et al teach that paclitaxel (See column 8, line 29) is suitable for the use as the therapeutic agent for coating medical devices including catheters (See column 8, line 19) by SCF processing (See column 3, lines 52-65); and the therapeutic agent can be may be mixed with SCF to form a true solution or may be in a suspension of particles (See column 9, lines 35-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used paclitaxel as the therapeutic agent in Greiner in view of Allen et al and Smith with the expectation of providing the desired coated biocompatible medical device, since Mehta et al teach that paclitaxel is suitable for the use as the therapeutic agent for coating medical devices including catheters by SCF processing.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used less soluble material such as colloidal solutions or suspensions in Greiner in view of Allen et al and Smith if there is no need to provide very fine powders for deposition as in case of Greiner.

8. Claims 8, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner (EP 405 284 A2) in view of Allen et al (US 6,495,204) and Smith (US 4,734,451), further in view of Scott et al (US 5,383,928), further in view of Lambert (US 5,900,246) and Davidson (US 5,954,724), and further in view of Mehta et al (US 6,627,246).

Combination of Greiner, Allen et al, Smith, Scott et al, Lambert and Davidson, as applied above, fails to teach that the therapeutic is combined with a carrier coating material (Claim 8); the therapeutic is interfaced with a coating prior to interfacing the therapeutic with supercritical fluid (Claim 32).

As was discussed above, Scott et al show that coating a medical device with drug-polymer combination is functionally equivalent to coating a metal medical device first with a polymer, then applying drug to the medical device are for the local delivery of drugs (See column 3, lines 53-65). Mehta et al teach that drug-polymer combination coating of a medical device including metallic stents, catheters (See column 8, lines 5-7, 19) with can be carried out using SCF processing (See column 3, lines 52-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coating a catheter using a drug-polymer combination in a method of Greiner, Allen et al, Smith, Scott et al, Lambert and Davidson instead of coating a metal medical device first with a polymer, and then applying drug to the medical device, with the expectation of providing the desired local delivery of drugs, since Scott et al show that coating a medical device with drug-polymer combination is functionally equivalent to coating a metal medical device first with a polymer, and then applying drug to the medical device are for the local delivery of drugs; and Mehta et al teach that drug-polymer combination coating of a medical device including metallic stents, catheters with can be carried out using SCF processing.

Allowable Subject Matter

9. Claims 12-15 are allowed.

The following is an examiner's statement of reasons for allowance: Claim 12 is allowed because the prior art of the record does not teach or suggest swelling a coating on a medical device prior to exposing the coating to SCF interfaced with therapeutic.

Claims 13-15 are allowed as further limiting allowed claim 12.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

10. Applicant's arguments with respect to claims 1-15, 21-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is (571) 272-1429. The examiner can normally be reached on Mo-Thur. 9:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (571) 272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ELENA TSOY
PRIMARY EXAMINER

Elena Tsoy
Primary Examiner
Art Unit 1762

October 14, 2004